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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,787	01/06/2004	Alberto Guillermo Suzarte Paz	024273-00001	8586
4372 7590 06/06/2008 ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036				
EXAMINER ROGERS, JAMES WILLIAM				
ART UNIT		PAPER NUMBER		
1618				
NOTIFICATION DATE		DELIVERY MODE		
06/06/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary

Application No.

09/743,787

Applicant(s)

SUZARTE PAZ ET AL.

Examiner

JAMES W. ROGERS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
4a) Of the above claim(s) 7-10 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 11 and 12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Any objection/rejection from the previous office action filed 01/28/2008 not addressed in the action below has been withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 4,740,376), for the reasons set forth in the previous office action filed 01/28/2008.

Response to Arguments

Applicant's arguments filed 04/28/2008 have been fully considered but they are not persuasive. Applicants assert that the examiner improperly concluded that all water is evaporated under the melt conditions used to produce the polyvinylacetate (PVAc) and would thus obviously be less than 1.5%. Applicants further state that their claimed invention is not restricted to methods to form PVAc which use molten techniques. Applicants further assert that the examiner incorrectly assumes that the PVAc of Yang would contain very low quantities of impurities and contaminants since Yang provides no disclosure of this. Applicants also assert that the claimed method is characterized by the use of vacuum and slow stirring at certain temperature. Applicants lastly assert that the mere similarity in MW between their claimed invention and Yang does not mean that the compounds would necessarily have the other claimed properties.

The relevance of these assertions is unclear. Firstly the examiner would like to clarify that the claims are drawn to a method of producing a solid pharmaceutical

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preparation not a method of producing PVAc, as such the examiner does not have to search for process to produce the PVAc rather the examiner must only search for PVAc that meets all of the claimed limitations for the polymer itself such as MW, Tg and impurity content. As noted before since PVAc was commercially purchased and added as an ingredient to an encapsulation material it would be obvious that by controlling the melt temperature PVAc could essentially be free of water, since it was commercially available and was further processed by melt with the other ingredients of the composition. It is further noted by the examiner that since the claim is drawn to a method of producing a composition which can be a solution, applicants have not excluded that this solution could be aqueous. Thus whether or not PVAc contains some water would be of little relevance if the substantially water free PVAc is added to a pharmaceutical preparation that can include water. In regards to applicants assertion that the examiner erred in stating that the residual monomer content of PVAc would be as low as currently claimed, it is noted by the examiner that the melt conditions employed by Yang used a temperature of about 85°C, well above the bp of vinyl acetate (VAc) which has a bp of around ~73°C. Thus by the melt processing it would be obvious that essentially any amount of residual monomer VAc present within the commercially bought PVAc would have boiled off during processing. Furthermore as noted in the previous office action since PVAc was commercially bought it would be obvious to one of ordinary skill in the art to select a commercially available PVAc which would have low impurity content since the polymer is used in an oral pharmaceutical formulation. It is considered to be ordinary and routine experimentation by the examiner

for one of ordinary skill in the art to purify a polymer to a high degree if it is to be used in an orally administrable dosage form. It is further noted by the examiner that applicants arguments are conclusionary in nature about the amounts of water and impurities and applicants have not showed any experimental results in which the PVAc after processing into the pharmaceutical formulations of Yang would not have the claimed residual impurities and water content. Regarding applicants assertion that it is improper to assume that since the MW of Yangs PVAc is similar to their claimed MW that the polymers would have the same properties, as noted in the last action it is inherent that if a polymer is comprised of the same structure and the same MW it will have the same physical properties including glass transition temperature.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991), cited by applicants), for the reasons set forth in the previous office action filed 01/28/2008.

Response to Arguments

Applicant's arguments filed 04/28/2008 have been fully considered but they are not persuasive. Applicants assert that the examiner improperly concluded that all water is evaporated under vacuum desiccator conditions used to produce the PVAc microspheres which would obviously lead to a water content less than 1.5%. Applicants further state that why it may be the case that water is essentially eliminated by the process above it is not an industrial process suitable for purifying a polymer whose use is not restricted to the production of microspheres. Applicants lastly assert that the mere

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similarity in MW between their claimed invention and Sa does not mean that the compounds would necessarily have the other claimed properties.

The relevance of these assertions is unclear. Sa does not use water in the method to produce the microspheres and any water present within the commercially bought PVAc would have been removed during filtration with n-hexane and during the drying process in the vacuum desiccator. Regarding applicants assertion that their process is an industrial process and is not restricted to production of microspheres, as currently amended applicants claims do not preclude the use of non-industrial processes to produce the pharmaceutical formulation nor have applicants provided evidence besides conclusionary statements as to why Sa does not teach a process that could be scaled up to an industrial process. Regarding applicants assertion that it is improper to assume that since the MW of Sa PVAc is similar to their claimed MW that the polymers would have the same properties, as noted in the last action it is inherent that if a polymer is comprised of the same structure and the same MW it will have the same physical properties including glass transition temperature. It is further noted by the examiner that applicants arguments are conclusionary in nature on the amounts of water and impurities and applicants have not showed any experimental results in which the PVAc after processing into the pharmaceutical formulations of Sa would not have the claimed residual impurities and water content.

Claim 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 4,740,376) in view of Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991)), for the reasons set forth in the previous office action filed 01/28/2008.

Response to Arguments

Applicant's arguments filed 04/28/2008 have been fully considered but they are not persuasive.

Applicants assert for the reasons above neither Yang nor Sa teach their claimed invention nor do the references cure each others deficiencies.

For the reasons established above the examiner does believe that Yang and Sa do disclose applicants currently claimed invention in combination and the combination would have been obvious to one of ordinary skill in the art.

Conclusion

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Application Number

Application/Control No.

09/743,787

Examiner

JAMES W. ROGERS

Applicant(s)/Patent under
Reexamination

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1618